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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,951	07/07/2000	GEORGE R. PETTIT	5379-US	4537

7590

11/26/2001

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 11/26/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/582,951

Applicant(s)

Pettit

Examiner

David Lukton

Art Unit

1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 13, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Pursuant to the directives of paper No. 9 (filed 9/13/01), claims 1-3, 8, 15 have been amended, and claims 16-18 have been added. claims 1-18 are pending.

Applicants' arguments filed 9/13/01 have been considered and found persuasive in part

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The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 9-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 3 is drawn to a method of inhibiting epidermal and systemic infections resulting from contact with *Cryptococcus neoformans*. This phrase is interpreted to mean that applicants are asserting that the condition of a patient who is infected with *Cryptococcus neoformans* will improve if administered one of the claimed compounds. As such, the claim is no different (from the standpoint of enablement) than if it had recited *a method of treating a fungal infection in a human patient*. Applicants have shown only that *in vitro* inhibition of fungal growth can occur. However, effective therapy of a fungal infection

in an elderly, ill patient is another matter altogether. There is the matter of anatomical localization and selective toxicity, as well as bioavailability and biodistribution. Then there is the situation of immune-compromised patients. Fungal infections are common in immune-compromised patients. One pertinent question here is, are applicants confident that if an emaciated, comatose patient with full-blown AIDS and infected in every tissue with *Cryptococcus neoformans* were administered a few doses of the claim 1 compounds, the patients' condition would improve? Is it applicants view that of the persons infected with fungi who had received several dosages of a compound which had been shown to inhibit fungal growth *in vitro*, none have subsequently died? The reality is that *in vitro* inhibition of fungi or bacteria is not a reliable predictor of what will happen in the seriously ill patient.

The extrapolation from the petri dish to the intact human is "unpredictable", and "undue experimentation" would be required to determine the circumstances, if any, that might exist such that benefit would accrue to the ill patient stricken with a fungal infection.

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Claims 1-18 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 1, line 2, "fungi" should be - - fungus - - .
- Claim 2 equates "fungal growth" with *Cryptococcus neoformans*, which is not accurate.

- Claim 3 makes reference to an "epidermal" infection. However, a "host" could be a plant or animal, insect or fish, prokaryote or eukaryote. Not all organisms have an epidermis; accordingly, a claim which makes reference to an epidermis should be limited to a mammal (or perhaps another class of organisms for which there is descriptive support).
- Claim 3 is drawn to a method of inhibiting epidermal and systemic infections resulting from contact with *Cryptococcus neoformans*. First, it is not possible to inhibit a state of being, only a process. For example, one can inhibit the formation of rust, but one cannot inhibit rust *per se*. One can inhibit the process of reproduction of a fungus, or of several fungi, but one cannot inhibit a fungus *per se*. As another example, one can inhibit proliferation of tumor cells, but one cannot inhibit cancer *per se*. Similarly, it is not possible to inhibit a fungal infection, since a fungal infection is a state of being, rather than a process. From the perspective of §112, second paragraph, the term "treatment" would be better than inhibition, if reference is being made to a fungal infection. [However, whether the phrase "inhibiting a fungal infection" is used, or the phrase "treating a fungal infection" (or equivalent), the claim will still be rejected for lack of enablement].
- Claim 3 equates "fungal growth" with cryptococcus, which is not correct.
- In each of claims 4-7, 11-14, the phrase "said active ingredient" lacks antecedent basis.
- In claim 16, line 5, the phrase "said fungal growth" is recited. However, under one interpretation, this phrase lacks antecedent basis. It is suggested that the following phrase be used instead: - - growth of said fungus - - .
- In each of claims 8 and 15, the following phrase is recited:
"said carrier said carrier".
This is an obvious typographical error
- Claim 9 recites that the "host" of the previous claims is limited to a mammal. Claim 4, which is dependent on claim 9, is drawn to "said host". Accordingly, it would be more appropriate to either make claim 4 dependent on claim 3, or else, that the "host" in claim 4 be limited to mammals. The same deficiency afflicts each of claims 5-7, and claims 11-14.



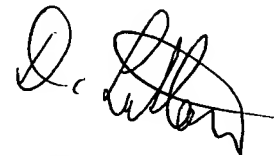
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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800